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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,053	03/13/2003	Thomas Woods Keough	7379M	6283

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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,053	KEOUGH ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 11* is/are pending in the application.

4a) Of the above claim(s) *8-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/28/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-5, 7, and 11. Claim 11 is newly added. Claim 6 has been cancelled. Claims 8-10 are again withdrawn, without traverse, from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Claims 1-5 and 7 are currently amended.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement filed 1/28/02 has been considered in full.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 11 are directed to methods for "sequencing a polypeptide." As these claims do not recite any steps directed to "sequencing," it is unclear in what way the steps of the instant claims 1 and 11 achieve the purpose of the preamble. Clarification is requested. It is noted that instant claims 1 and 11 recite a step of "analyzing" a fragmentation pattern, however, this is not a step directed to determining a sequence, as analyzing a fragmentation pattern as in claim 1 could simply be determining how many fragments are present.

Claim 1, step (a), has been amended to recite the limitation "pKa is less than about 2, when coupled with the polypeptide or at least one peptide of the polypeptide." It is unclear if "when coupled" is intended to be an actual method step (e.g. where pKa is measured) or a further limitation of the acid moiety of instant claim 1. Clarification is requested. It is noted that applicant has stated in the response filed 4/12/2006 (p.5) that "when coupled" means that the pKa's of the acidic moieties are defined as measured after they are covalently bonded with a polypeptide or peptide. If applicant intends the recited coupling to be a method step, the claim should re-written such that this is clear. Currently there is no step directed to measuring pKa values. Therefore, for purposes of examination with regards to prior art, the limitation "pKa is

less than about 2, when coupled with the polypeptide or at least one peptide of the polypeptide" has been interpreted as "pKa is less than about 2."

Amended claim 1 and newly added claim 11 recite the limitation "pKas of less than about 2". This rejection is reiterated as the applicant's response was not found to be persuasive regarding "pKas of less than 2." The applicant's response to the previous rejection [p.6 of the response] is noted. However, because "coupling" a moiety to a peptide may change the pKa of the peptide (or moiety), one still has to know the pH of the solution a compound is in, in order to determine the pKa of that compound, regardless of whether the compound is derivatized. Therefore, this limitation is meaningless without information related to pH. Clarification is requested.

Newly added claim 11 recites the limitation "providing...analyte...with a mass spectra". It is unclear as to the intended meaning of "providing" in this context. Clarification is requested.

Newly added claim 11 recites the limitation "said coupled polypeptide". There is lack of antecedent basis for this limitation. However, claim 11 recites a polypeptide. Clarification is requested. Claims 2, 4, and 7 are rejected as they depend directly or indirectly from claim 1.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, and 11 are rejected under 35 U.S.C. 102 (b) as being anticipated by Knierman et al. (Rapid Communication is Mass Spectrometry, 1994, Vol. 8, 1007-1010), as supported by the Physical Science Information Gateway: Chemical Data Tables, Copyright 2002, p.1-2, website: http://www.psigate.ac.uk/newsite/reference/chemdata/5.html.

Applicant's arguments with regards to the instant invention, filed 04/12/2006, that the Knierman et al. does not teach a method of "derivatizing with at least one acidic moiety having a pKa of less than about 2 when coupled with a polypeptide or at least one peptide of the polypeptide" have been fully considered but they are not persuasive for reasons set forth below. This rejection is necessitated by amendment.

As set forth in the previous office action, Knierman et al. clearly teach N-terminus derivatization of synthetic peptides (Abstract), as in instant claim 1, by adding HCl (p.1007, col. 2, lines 8-12), which equates to the use of at least one acidic moiety with a pKa of less than 2, as in instant claims 1, 4, 5, and 11. It is noted that derivatization inherently includes an intermediate stage where the acid "couples" to the N-terminus, which equates to a "coupling" stage. Furthermore, it is noted that HCl has a pKa that is negative [See: http://www.psigate.ac.uk/newsite/reference/chemdata/5.html], which is clearly less than 2 as required by instant claims 1 and 11. Therefore, the examiner maintains that Knierman et al. does indeed teach a method of derivatizing with at least one acidic moiety having a pKa of less than about 2 when coupled with a polypeptide or at least one peptide of the polypeptide. Knierman et al. further teach the following limitations introduced by amendment: chemical (i.e. acidic) digestion, as in instant claim 5; mass spectra characterized predominantly by fragments containing the original C-terminus of the peptide [Fig. 1 (e) and (f), and Table I], which equates

to "y-ions" as in instant claim 11. It is noted that the Specification [p.16] discloses y-ions indicate ionized fragments containing the original C-terminus of the polypeptide or peptide.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following prior art publications are the basis for executing this rejection:

Claims 1, 2, and 4-6 are rejected under 35 U.S.C. are rejected under 35 U.S.C. 103(a) as being anticipated by Knierman et al. (Rapid Communication is Mass Spectrometry, 1994, Vol. 8, 1007-1010), as applied to claims 1, 4, 5, and 11, above, in view of Roth et al. (Mass Spectrometry Reviews, 1998, 17, 255-274).

Applicant's arguments with regards to the instant invention, filed 04/12/2006, that the combination of Knierman et al. and Roth et al. do not teach a method of "derivatizing with at least one acidic moiety having a pKa of less than about 2 when coupled with a polypeptide or at least one peptide of the polypeptide" have been fully considered but they are not persuasive for the reasons set forth above. This rejection is necessitated by amendment.

Knierman et al. teach methods by which a sequence-dependent peptide fingerprint can be rapidly obtained upon partial hydrolysis of peptides subsequent analysis with MALDI, as set forth above. Knierman et al. do not specifically teach the use of MALDI-PSD for peptide analysis or the use of enzymatic digestion.

Roth et al. teach the use of MALDI-PSD mass spectrometry for peptide analysis (Fig. 7, p. 263), as in instant claim 2. Roth et al. also teach the use of acids or enzymes to digest peptides, generating peptide derivatives (p. 259, col. 2, lines 40-46), as in instant claim 6.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the invention of Knierman et al. with the use of MALDI-PSD at taught by Roth et al., where the motivation would have improve the fragmentation pattern of derivatized peptides using enzymatic degradation of peptides at taught by Roth (p. 259, lines 25-30). One of ordinary skill in the art would have had a reasonable expectation of successfully combining the derivatization method of Knierman et al. with the use of enzymatic digestion and MALDI-PSD spectrometry as taught by Roth et al. because both teach methods of mass spectrometry for peptide analysis.

Claims 1 and 7 are rejected under 35 U.S.C. are rejected under 35 U.S.C. 103(a) as being anticipated by Knierman et al. (Rapid Communication is Mass Spectrometry, 1994, Vol. 8, 1007-1010), as applied to claims 1, 4, 5, and 11, above, in view of Stolowitz et al. (Analytic

Biochemistry, 1989, Vol. 1, Issue 1, p.113-119) and Ripin et al., 2005, p.1-6, Website: http://daecr1.harvard.edu/pdf/evans_pKa_table.pdf).

Knierman et al. teach methods by which a sequence-dependent peptide fingerprint can be rapidly obtained upon partial hydrolysis of peptides subsequent analysis with MALDI, as set forth above. Knierman et al. do not specifically teach the derivatization of polypeptides with sulfonic acid or disulfonic acid derivates, as in instant claim 7.

Stolowitz et al. teach a method of protein sequencing comprising derivatizing the N-terminus of polypeptides using sulfonic acid chlorides [Abstract, p.119, Col. 1, ¶ 1], as in instant claim 7. Stolowitz et al. also teaching steps directed to coupling of acidic moieties with polypeptides [Fig. 3] and mass spectral analysis of derivatives [Fig. 2 and 4]. It is noted that Ripin et al. teach pKa values of sulfonic acid which are less than 2, as required by instant claim 1 (Ripin et al., http://daecr1.harvard.edu/pdf/evans_pKa_table.pdf)

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the invention of Knierman et al. with the use of sulfonic acid for derivatizing polypeptides as at taught by Stolowitz et al., where the motivation would have been to use derivatizing reagents that are inexpensive, hydrolytically stable, and afford highly stable derivatives [Stolowitz et al., p.119, Col. 1, ¶ 1]. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the derivatization method of Knierman et al. with the use of sulfonic acid reagents as taught by Stolowitz et al. because both teach methods of derivatizing polypeptides with acids and mass spectral analysis.

Double Patenting Rejection

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 1-2, and 5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 10 of co-pending Application No. 09/863,786. It is noted the claims of 09/863,786 will issue as a patent on 7/11/06. Reference claims 1 and 2 correlate to instant claim 1, reference claim 3 correlates to instant claim 2, and reference claim 10 correlates to instant claim 5. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention, thus the inventions have overlapping embodiments. It is noted that reference claim 1 is directed to a method of identifying a polypeptide. Therefore applicant's amendments to instant claims 1-2 and 5, specifically where

instant claim 1 is now directed to a method of "sequencing a polypeptide," do not overcome this rejection.

Co-pending Application No. 09/863,786 does not teach the limitation of MALDI-PSD. However, Roth et al. teach methods of peptide analysis using MALDI-PSD (see above).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the invention of the co-pending Application No. 09/863,786 with Roth et al., where the motivation would have improve the fragmentation pattern of derivatized peptides (Roth et al, p. 259, lines 25-30).

Applicants did not address this rejection in the response filed 04/12/2006, and the claim amendments filed with the response do not overcome the rejection, therefore it is maintained.

CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner
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MARJORIE A. MORAN
PRIMARY EXAMINER

6/26/06